

REMARKS

Claims 1-20 and 28-43 are currently pending in the application. Of these, claims 1, 8, 14, 16, 28, 31-33 and 41 are currently amended. Claims 9, 10, 28-30, 38 and 39 are presently withdrawn from consideration. New claims 42 and 43 have been added. The claim amendments and new claims do not present new matter. *See, e.g.*, para. 173 (sharpened ends); para. 174 (small, low profiles of about 0.5mm to 1mm in diameter). Claim 14 has been amended to now depend from claim 13 in order to address the objection raised on page 2 of the Office Action. Claims 38 and 39 are now identified as “Withdrawn,” per the Office Action remarks on page 2 of the Office Action.

Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Withdrawn Claim Rejections

Applicant appreciates that the prior rejections based on U.S. Patent No. 6,277,117 to Tetzlaff *et al.* has been withdrawn.

II. Claims 1-8, 11-20, 31-37, 40 and 41 Are Novel Over Gadsby

The current Office Action rejects independent claims 1, 16 and 34 and respective dependent claims 2-8, 11-15, 17-20, 31-33, 35-37, 40 and 41 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,309,090 to Gadsby *et al.* (“Gadsby”). A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP §2131. Applicant respectfully traverses the rejection, since Gadsby fails to anticipate any claim of the subject application.

Initially, the Office Action states that the electrode 12, described by Gadsby is a “carrier moveable between an unstressed state and a deflected and stressed state,” as recited in claim 1, and “a carrier movable between an unstressed state and a stressed state,” as recited in claim 8. Office Action (p. 3 (claims 1 and 8)). Gadsby refers to the electrode 12 as the entire device. (Gadsby, col. 3, lines 53-60; Fig. 1). The entire device 12, however, is not moveable as recited in the respective claims. Rather, Gadsby explains that the resilient dome 16 (*i.e.*, a component of the electrode device 12) is moveable between first and second positions. (Gadsby, col. 3, lines 56-58).

Gadsby fails to disclose, teach or suggest a carrier that is movable and “a tissue stimulation element supported by the carrier,” or “a tissue engagement device carried by the carrier, the tissue engagement device being configured to secure itself to tissue and secure the carrier to the tissue in the deflected and stressed state,” as recited in claim 1. The Office Action states that the collection of penetration tines 18 is the “tissue stimulation element” and the “tissue engagement device” is the conductive pad 22. However, Gadsby describes and illustrates a resilient dome 18 and a conductive pad 22 as different components that are separated from each other, i.e., the pad 22 is housed in a cavity 26. (Gadsby, Fig. 1, Fig. 3; col. 3, lines 63-65). Therefore, based on the assumptions presented in the Office Action, Gadsby does not disclose, teach or suggest both a tissue stimulation element supported by the carrier and a tissue engagement device carried by the carrier.

The Office Action states that the penetration tines 18 in Gadsby form “a tissue stimulation element.” Office Action (p. 3). Gadsby, however, does not disclose, teach or suggest that the tines 18 are used for stimulation or capable of stimulation. Instead, Gadsby explains that the device 12 is a “monitoring” device and further explains that “[t]he invention is directed toward an electrode that performs skin preparation prior to receiving biopotentials. The electrode prepares the patient’s skin by substantially penetrating the skin” using penetration tines 18 in order to reduce skin impedance and the potential to produce motion artifacts. (Gadsby, col. 2, lines 45-52). Gadsby also explains that puncturing skin before a procedure “prevents the possibility of skin laceration due to electrode movement with respect to the skin.” (Gadsby, col. 3, lines 7-10). Thus, the penetration tines 18, individually and collectively, are not tissue stimulation elements, particularly considering that the tines 18 are used before any signals are monitored.

Nevertheless, even assuming *arguendo* that the penetration tines 18 somehow can be construed as stimulation elements, they do not form a tissue engagement device “configured to secure itself to tissue and secure the carrier to the tissue in the deflected and stressed state” as recited in claim 1. In contrast, Gadsby explains “[u]pon application of a force to the dome, the dome moves from a first position to a second position, forcing penetration tines into the patient’s skin. Upon removal of the force, the dome moves back to its original position configuration, withdrawing the penetration tines from the patient’s skin.” Gadsby (Abstract) (emphasis added). Thus, the penetration tines 18 are not secured to tissue and instead are immediately withdrawn upon removal of force. This is consistent with Gadsby illustrating and describing conical-shaped

tines 18 that penetrate the skin by approximately 0.5mm. Gadsby (col. 4, lines 38-39; Fig. 1). Such tines 18 are not suitable for securing themselves to skin. *See also*, Gadsby (col. 4, lines 20-24, 29-31 (fully withdrawn after pressure released from dome 16); col. 4, line 57 - col. 6, line 2 (tines are conical projections). Moreover, Gadsby explains that it is not desirable to have tines 18 secured to tissue since “[r]emoval of the tines from the skin before receiving biopotentials prevents the possibility of skin laceration due to electrode movement with respect to the skin.” Gadsby (col. 3, lines 7-10).

Turning to claim 8, Gadsby also fails to disclose, teach or suggest a carrier that is movable, “a tissue stimulation element supported by the carrier” and “first and second tissue piercing members carried by the carrier and configured to secure the carrier to tissue in the stressed state.” The Office Action states that the penetration tines 18 form a “tissue stimulation element” and that pointed tips of the tines 18 are “first and second tissue piercing members ...” as recited in claim 8. However, as discussed above, Gadsby does not disclose, teach or suggest that the tines 18 are used for, or capable of, stimulation. Instead, Gadsby explains that the device 12 is a “monitoring” device and that the tines 18 are used to penetrate skin 30 in order to reduce skin impedance and motion artifacts prior to monitoring biopotentials. Further, the penetration tines 18 are withdrawn and not configured to “secure the carrier to tissue” as recited in claim 8. Gadsby (Fig. 1, Abstract, col. 2, lines 45-52, col. 3, lines 7-10 (removal of tines), col. 4, lines 20-24, 29-31 (fully withdrawn); col. 4, line 57 - col. 6, line 2 (tines are conical projections). Therefore, Gadsby does not disclose, teach or suggest “a tissue stimulation element supported by the carrier” and “first and second tissue piercing members carried by the carrier and configured to secure the carrier to tissue in the stressed state” as recited in claim 8.

Turning to claim 13, Gadsby fails to disclose, teach or suggest a “tissue stimulation element” and means, associated with the tissue stimulation element, “for securing the surgical apparatus to the tissue structure ...” Rather, as discussed above, Gadsby does not disclose, teach or suggest that the tines 18 are used for, or capable of, stimulation. Instead, Gadsby explains that the device 12 is a “monitoring” device and that the tines 18 are used for penetrating skin 30 in order to reduce skin impedance and motion artifacts prior to monitoring biopotentials. Further, the tines 18 are not “for securing the surgical apparatus to the tissue” since the tines 18 are withdrawn upon removal of force and removed from the skin prior to any monitoring. (Fig. 1, Abstract, col. 2, lines 45-52, col. 3, lines 7-10 (removal of tines), col. 4, lines 20-24, 29-31 (fully withdrawn); col. 4, line 57 - col. 6, line 2 (tines are conical projections).

Turning to claim 16, Gadsby fails to disclose, teach or suggest a “tissue stimulation element” and “an anchor, associated with the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by piercing the tissue and press the stimulation element against the tissue.” The Office Action states that the tips of the penetration tines 18 form the “anchor” as recited in claim 16. However, as discussed above, Gadsby does not disclose, teach or suggest that the tines 18 are used for, or capable of, stimulation. Instead, Gadsby explains that the device 12 is a “monitoring” device and further explains that the tines 18 are used for the specific purpose of penetrating skin 30 in order to reduce skin impedance and motion artifacts prior to monitoring biopotentials. Further, the tines are not an “anchor” and do not “secure the surgical apparatus to the tissue” since the tines 18 are withdrawn upon removal of force and are removed from the skin prior to any monitoring. Gadsby (Fig. 1, Abstract, col. 2, lines 45-52, col. 3, lines 7-10 (removal of tines), col. 4, lines 20-24, 29-31 (fully withdrawn); col. 4, line 57 - col. 6, line 2 (tines are conical projections)).

Turning to claim 34, Gadsby does not disclose, teach or suggest “first and second tissue stimulation elements” as recited in claim 34. Rather, as discussed above, Gadsby explains that the device 12 is a “monitoring” device and that the tines 18 are used for penetrating skin 30 in order to reduce skin impedance and motion artifacts prior to monitoring biopotentials, and that the tines 18 are withdrawn before receiving biopotentials. Gadsby (Fig. 1, Abstract, col. 2, lines 45-52, col. 3, lines 7-10 (removal of tines), col. 4, lines 20-24, 29-31 (fully withdrawn); col. 4, line 57 - col. 6, line 2 (tines are conical projections)).

Gadsby also fails to disclose, teach or suggest “a flexible carrier movable between an unstressed state and a deflected and stressed state and including a first end portion that carries the first tissue stimulation element, a second end portion that carries the second tissue stimulation element, and a curved interior portion located between the first and second end portions and configured such that the curved interior portion will be in spaced relation to the tissue surface when the end portions are in contact with the tissue surface and the carrier is in the unstressed state” as recited in claim 34.

Initially, the Office Action states that the electrode 12, described by Gadsby is a “flexible carrier moveable between an unstressed state and a deflected and stressed state,” as recited in claim 34. However, Gadsby refers to the electrode 12 as the entire device, (Gadsby, col. 3, lines 53-60; Fig. 1), and the entire device 12 is not moveable. Rather, Gadsby explains that the resilient dome 16 is moveable between first and second positions. (Gadsby, col. 3, lines 56-58).

Further, Gadsby explains that the penetration tines 18 “project from the inner surface of the dome” and that the dome 16 has a curved shape. Gadsby (Fig. 1). The basis of the rejection is not clear, since Gadsby discloses penetration tines 18 extending from a curved surface of the dome 16, but claim 34 refers to a tissue engagement device (configured to secure the carrier to the tissue) that is carried by the “curved interior portion” and, in addition, “first and second end portions” each of which carries a stimulation element.

Further, Gadsby fails to disclose, teach or suggest “the curved interior portion will be in spaced relation to the tissue surface when the end portions are in contact with the tissue surface and the carrier is in the unstressed state” as recited in claim 34, which also recites that the first and second end portions carry respective stimulation elements. The Examiner appears to have the opinion that the “first and second end portions” are part of the dome 16 and that the “stimulation elements” are tines 18. Gadsby, however, cannot support the rejection, since Gadsby explains that when the dome 16 is in its first position (the alleged “unstressed” state), the penetration tines 18 are not in contact with the skin 30. Gadsby (Fig. 3). Rather, the tines 18 are positioned above the skin 30. The tines 18 contact the skin 30 only when the dome 16 is in its second or compressed position (the alleged “stressed” state). Gadsby, (Fig. 4; col. 4, lines 12-24). Therefore, the tines 18 (the alleged stimulation elements) do not contact the skin when the dome is in its initial (alleged “unstressed” state). Consequently, the disclosure of Gadsby is not relevant to claim 34.

Additionally, even assuming *arguendo* that the penetration tines 18 can be construed as stimulation elements, they do not form a tissue engagement device “configured to secure the carrier to the tissue surface in the deflected and stressed state” as recited in claim 34. Rather, as discussed above, Gadsby explains “[u]pon application of a force to the dome, the dome moves from a first position to a second position, forcing penetration tines into the patient’s skin. Upon removal of the force, the dome moves back to its original position configuration, withdrawing the penetration tines from the patient’s skin.” (Gadsby, Abstract) (emphasis added). Thus, the penetration tines are not secured to tissue and instead are immediately withdrawn upon removal of force. Gadsby (Fig. 1; col. 4, lines 20-24, 29-31 (fully withdrawn after pressure released from dome 16); col. 3, lines 7-10; col. 4, line 57 - col. 6, line 2).

Further, Gadsby fails to disclose, teach or suggest dependent claim 3, which recites *inter alia*, “wherein the carrier includes first and second end portions and an interior portion and the carrier is configured such that the interior portion will be in spaced relation to the tissue when

the end portions are in contact with the tissue and the carrier is in the unstressed state.” The Office Action states that the penetration tines 18 form a stimulation element, but the tines 18 contact the skin 30 only when the dome 16 is in its second or compressed position (the alleged “stressed” state). Gadsby, (Fig. 4; col. 4, lines 12-24). Therefore, the tines 18 (the alleged stimulation elements) do not contact the skin when the dome is in its initial (alleged “unstressed”) state. Consequently, Gadsby is not relevant to claim 3.

Gadsby also fails to disclose, teach or suggest “wherein the tissue engagement device is configured to hold the interior portion of the carrier substantially against the tissue” as recited in claims 1 and 36. In contrast, Gadsby explains that a resilient dome 16 is manually moved which, in turn, causes tines 18 to penetrate tissue. Gadsby does not disclose, teach or suggest any tissue engagement device that holds an interior portion of a carrier substantially against the tissue, particularly considering that Gadsby explains that the tines are withdrawn upon removal of force. Gadsby (col. 4, lines 20-25).

The deficiencies of the tines with respect to claims 11, 12, 14, 15, 17, 18, 29, 30 and 40 are discussed above, *i.e.*, the tines 18 penetrate the skin 30 to reduce skin impedance and reduce the potential for motion artifacts prior to monitoring biopotentials, and are removed prior to monitoring to prevent lacerations. (Gadsby, col. 3, lines 7-10).

In view of these substantial differences and deficiencies, Applicant respectfully requests that the rejection of independent claims 1-8, 11-20, 31-34 and 36-41 over Gadsby be withdrawn.

III. New Dependent Claims 42 and 43 Are Novel Over Gadsby

New dependent claims 42 and 43 incorporate the elements and limitations of respective independent claims 1 and 13 and, therefore, are also allowable. MPEP §2143.03. Further, with regard to claims 1 and 13, the Office Action states that the conductive pad 22 is the “tissue engagement device” as recited in claims 1 and 13. The conductive pad 22 does not have “a sharpened end for piercing tissue” as recited in claims 42 and 43.

CONCLUSION

Applicant respectfully requests entry of this Amendment, and submits that doing so will place the application in condition for allowance in view of the forgoing amendments and remarks. If there are any remaining issues that can be resolved by telephone, Applicant invites the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

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Dated: April 27, 2007

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